

REMARKS

This Reply under 37 C.F.R. §1.111 accompanies a Request for Continued Examination and addresses the issues of the final Office Action mailed August 14, 2006 (hereinafter the "Instant Office Action"). Claim 17 and the dependent claims 19-22, 25, 28 and 29 are under examination all of which stand rejected. No withdrawn claim has been amended and no new claim has been added.

1. Claims 49-62, which were added to the instant application in Applicant's prior submission, have been withdrawn from consideration. Applicant respectfully requests the rejoinder thereof, as well as those claims previously withdrawn, in the event that any one of the pending claims is found to be patentable.

2. Applicant is grateful for the consideration of his arguments in response to the Office Action mailed on December 5, 2005 and for the withdrawal of rejections set forth therein.

3. Claim 17 and the dependent claims 19-22, 25, 28 and 29 stand rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. In particular, with respect to Claim 17, the Examiner concluded that he has not found *ipsis verbis* support in the specification for the negative claim limitation to exclude polyesters which are "not a carboxy-terminated polyester." The Examiner further notes that "as 'carboxy-terminated polyesters' are not positively recited in the specification, they may not be explicitly excluded in the claims." See page 3 of the Instant Action.

Applicant's response to the Examiner's conclusion is two-fold. First, there is *ipsis verbis* support in the specification for the negative claim limitation. Second, even if it were assumed,

arguendo, there is no *ipsis verbis* support (i.e., no word-for-word recitation of “carboxy-terminated polyester”), under the doctrine of inherency, the application describes the invention in a manner such that one skilled in the art would necessarily realize that the applicant was in possession of the invention.

The *ipsis verbis* support in the specification for the negative claim limitation is found at page 19, lines 25-27, as follows: “Water insoluble salts of peptides with carboxy functionalized PLGA were prepared as described in US Patent No. 5,672,659 the teachings of which are incorporated herein by reference.” MPET §2163.07(b) provides that “[t]he information incorporated [by reference to the document in the text of the specification] is as much a part of the application as filed as if the text was repeated in the application, and should be treated as part of the text of the application as filed.” *See, also*, 37 C.F.R. §1.57, MPEP §§ 608.01(p) and 2181.

The following is FIG. 2 as found in the '659 Patent:

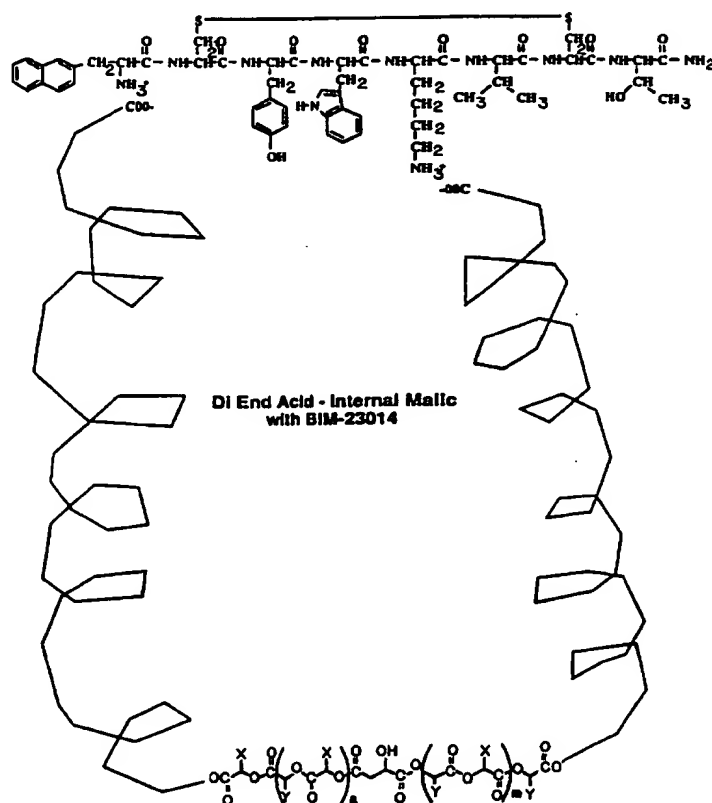
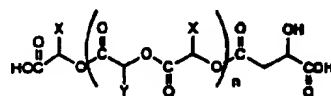


FIG. 2 of the '659 Patent is "an illustration of an ionic molecular conjugate depicting the chemical interactions between the lactide/glycolide (malic type) copolymer and Somatuline (BIM-23014)." See column 5, lines 6-9. This corresponds to page 20, lines 1-3, of the present application, wherein it is stated that "[i]n a typical experiment 4 g of p(dl-lactide-co-glycolide) having Mn= 5560 and Mw= 12200, acid and polymer composition 70/30 dl-lactide/glycolide, prepared using 2% malic acid was dissolved in acetone." FIG. 2 of the '659 Patent is accompanied by the text "Di End Acid-Internal Malic with BIM-23014," and it clearly shows the "di end" or "carboxy-terminated" aspect of the polyester.

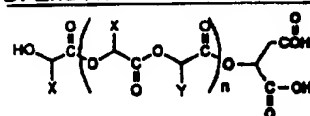
The following is FIG. 1 as found in the '659 Patent:

Forms of Lactate/ Glycolate-Type Polymers of Polycarboxylic Acid-Tipped Chains

LINEAR CHAINS

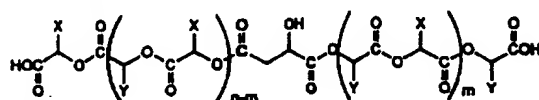


Di End Acid - Terminal Malic

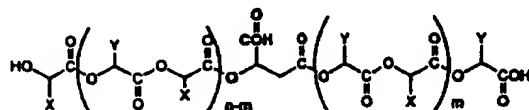


End Hydroxy - Terminal Malic

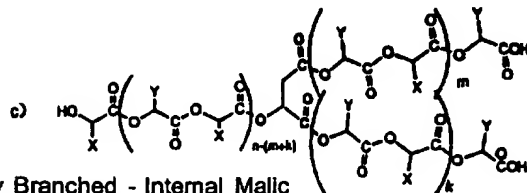
BRANCHED CHAINS



Di End Acid - Internal Malic



End Hydroxy - Internal Malic



Fully Branched - Internal Malic

Y= CH₃ for Lactic, H for Glycolic; X= H for Glycolic, CH₃ for Lactic
 Distribution of X + Y is formula dependent and polymerization dependent

All of the “Di End” “Terminal Malic” polyester chains depicted in FIG. 1 are “carboxy-terminated.”

In view of the abundant description – both text description and “drawings” illustrations of same – of “di end terminal malic” polyester chains in the ’659 Patent, which is expressly incorporated by reference into the present application, there is *ipsis verbis* support for the negative limitation to exclude polyesters which are “not a carboxy-terminated polyester.”

Even if it were assumed, *arguendo*, that there is no *ipsis verbis* support for the negative limitation in the specification, Applicant respectfully submits that one of ordinary skill in the art would have recognized that the allegedly missing subject matter (i.e., “carboxy-terminated polyesters”) would be *inherent* in the application. *See, e.g., Continental Can Co. USA v. Monsanto Co.*, 948 F.2d 1264, 1268-1269, 20 U.S.P.Q. 1746, 1749 (Fed. Cir. 1991).

First of all, as discussed above, the ’659 Patent is expressly incorporated by reference into the present application, and the ’659 Patent’s disclosure of “di end terminal malic” polyesters as depicted in FIGS. 1 and 2, would be clearly understood by one skilled in the art to be “carboxy-terminated polyesters.” The disclosure of the ’659 Patent is evidence that the ***necessary and only reasonable construction*** to be given the disclosure by one skilled in the art lends clear support to the negative limitation to exclude polyesters which are “not a carboxy-terminated polyester.”

Second of all, as discussed above, the present application, at page 20, lines 1-3, it is stated that “[i]n a typical experiment 4 g of p(dl-lactide-co-glycolide) having Mn= 5560 and Mw= 12200, acid and polymer composition 70/30 dl-lactide/glycolide, prepared using 2% malic acid was dissolved in acetone.” One skilled in the art would have understood that malic acid was used to *initiate* the polymerization. If the method of polymerization used was ring opening polymerization (commonly abbreviated “ROP”), then this will indeed result in a carboxy-

terminated polymer as the malic acid OH group initiates (i.e., anchors) the growing polymer chain while the COOH groups remain intact and so are left at the end of the completed chain. Furthermore, one skilled in the art would have understood that a carboxy terminal would result even if the other common method of polymer synthesis (commonly known as “polycondensation”) was used, in that although both the OH and COOH groups of the malic acid may initiate the polymerization in such case, the lactide and glycolide components – which would be at the other end of the chain – would be present with a COOH terminal, as these dimers open during the synthesis inserting lactic acid and glycolic acid units.

Moreover, it should be noted that Example 2(d), on pages 20-21 of the present application, it is stated that p(dl-LGA) was used, however, the same rationale applies to this situation as Example 2(a), on pages 17-18 of the present application.

As such, Applicant respectfully submits that there is *ipsis verbis* support for the negative limitation in view of the incorporation of the '659 Patent into the present application, and, in the alternative, under the doctrine of inherency, one of ordinary skill in the art would have readily understood that “carboxy-terminated polyesters” is necessarily and unambiguously disclosed in the present application. Applicant emphasizes that under either test, the disclosure of the '659 Patent is fully applicable on the determination of whether Applicant has complied with the requirements of 35 U.S.C. §112, second paragraph.

Request for Rejoinder

Applicant submits that claim 17 is a generic claim and based on the above arguments is in a condition for allowance. Upon the allowance of a generic claim, an Applicant is entitled to consideration of claims to additional species which are written in dependent form as provided for

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Filed : May 22, 2001
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by 37 C.F.R. §1.141. Applicant respectfully requests that withdrawal of claims 23, 24, 26, 27, 30-32, and 49-62 be rescinded and that said claims be reconsidered.

CONCLUSION

In view of the remarks herein, reconsideration of the Instant Office Action, rejoinder of the withdrawn claims and allowance of the pending and withdrawn claims are respectfully requested. Prompt and favorable action is solicited.


Should the Examiner Borin deem that any further action by the Applicant would put this application in order for acceptance, he is invited to telephone Applicant's attorney at (508) 478-0144 to facilitate prosecution of this application.

With the exception of the fee for the Petition for a one month extension under 37 C.F.R. §1.136(a) and the fee for the Request for Continued Examination under 37 C.F.R. §1.17(e), Applicant believes that no fees are due with this response, however, the Commissioner is hereby authorized to charge any additional fees associated with this communication or credit any overpayment to Deposit Account No. 50-0590.

Respectfully submitted,

Date:

12/14/06



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